VHA's Adverse Drug Event Reporting Program

Postmarketing drug surveillance is vital to reporting adverse drug events (ADE) to the FDA and VHA. A cornerstone of this approach is the collection and evaluation of reports of ADEs through voluntary reporting by healthcare professionals. The safety profile of a drug evolves over time as new information is discovered on a drug with its use in larger populations and subgroups not previously studied during clinical trials. ADE reports contribute to drug safety by triggering signals of potential problems that may lead to heightened awareness of drug reactions and further promote interdisciplinary problem solving of the drug's safety and attributes between pharmacists, physicians, nurses and other healthcare professionals. When VHA hospitals submit ADE reports to the FDA with duplicate reports to the VHA Central Office (PBMSHG), the minimum basic information required to ensure a complete ADE report for the FDA MedWatch Form 3500 http://www.fda.gov/medwatch/SAFETY/3500.pdf) is the following.

- Product Name(s) (if generic, include the name of the manufacturer) [BOX C]
- Concise description of the adverse event [BOX B.5]
- Date of event and Date of report [BOX B.3 & B.4]
- Drug start/stop dates [BOX C.3]
- Dose, frequency and route of administration [BOX C.2]
- Relevant lab values [BOX B.6]
- Biopsy/autopsy reports (if applicable)
- Patient demographics [BOX A]
- Confounders (other medical products; medical history) [BOX C.1 (2), C.10, B.7]
- Patient outcome [BOX B.2]
- Name of Reporter (FDA will ensure confidentiality if so indicated) [BOX E]
- For VHACO, Reporter Name should also include VHA facility name and address, Station Number, and VISN Number [BOX E]

For further information on ADE Reporting and Submission, contact:
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